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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,810	01/13/2004	Paul A. Wender	8400-0011	1195

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REED INTELLECTUAL PROPERTY LAW GROUP
1400 PAGE MILL ROAD
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EXAMINER

OWENS, AMELIA A

ART UNIT PAPER NUMBER

1625

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/757,810

Applicant(s)

WENDER ET AL.

Examiner

Amelia A. Owens

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/26/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-48 and 50-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6-48, 51-53 is/are allowed.
- 6) ☒ Claim(s) 2, 50, 54 and 58 is/are rejected.
- 7) ☒ Claim(s) 3-5 and 55-57 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 2-48,50-58 are pending.

Claim Rejections - 35 USC § 102

2. The rejection under 35 USC 102(a) has been dropped as applicants remarks, declaration are persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 2-5,54-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
4. Claims 2,50,54,58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

For paragraphs 3 and 4 above, the transitional term ‘comprising’, which is synonymous with ‘including’, ‘containing’, or ‘characterized by’, is inclusive or open-ended and does not exclude additional unrecited elements or method steps. *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) (‘comprising’ leaves ‘the claim open for the inclusion of unspecified ingredients even in major amounts’). See MPEP 211.03.

The apoptolidin and isoapoptolidin moiety are critical to the invention. The language allows for modification to the moiety not adequately supported by the specification.

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The term 'comprising' encompasses inclusions to the apoptolidin and isoapoptolidin moiety a description of which is not found in the specification.

Claim Objections

Claims 3-5,55-57 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Allowable Subject Matter

Claims 6-48,51-53 are allowed. USP 6548485 B2 teaches apoptolidin derivatives to treat tumors. See column 1 lines 35-58. Salmon et al, Understanding and exploiting the mechanistic basis for selectivity of polyketide inhibitors of F₀F₁-ATPase, PNAS, 97(26), pp.14766-14771, December 19, 2000, teach apoptolidin induces apoptosis in cells. See abstract, page 14766 column 1 lines 1-20. Structurally similar compounds would be expected to have similar properties. Thus, the one of ordinary skill in the art would expect the claimed apoptolidin and isoapoptolidin compounds to induce apoptosis in cancer cells.

The data in the specification in example 5/Table 5 is noted. The compounds inhibit F₀F₁-ATPase as does apoptolidin. The prior art neither teaches nor suggests the claimed compounds. In the absence of any evidence or apparent reason why the claimed compounds do not possess the disclosed utility, the allegation of utility in the specification must be accepted as correct. In re Kamal et al, 158 USPQ 320; Ex parte Krenzer, 199 USPQ 227.

Claim 16 provisos out apoptolidin and therefore distinguishes over the art. Motivation is lacking to modify apoptolidin to arrive at the claimed compounds.

Claim 26, position Q9 is different than for the Pennington et al reference, Organic Letters, 4(22) pp 3823-3825, (2002), thereby distinguishing over the art. Motivation is lacking to modify apoptolidin to arrive at the claimed compounds.

Claim 26 differs from claim 1 of USP 6548485 B2 in that the claimed ring is 21 members and the reference compound has 20 ring members; also the claimed compound has -OQ2 variable at position 23. Motivation is lacking to modify the reference to arrive at the claimed compound.

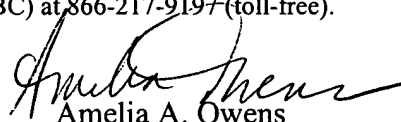
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Claim 51 has a benzopyrrole fused to the core apoptolidin ring at positions 10-13 thereby distinguishing over the apoptolidin compounds. Motivation is lacking to modify apoptolidin to arrive at the claimed compounds.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amelia A. Owens whose telephone number is 571-272-0690. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Amelia A. Owens

Primary Examiner

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